

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

KEIKO GORSKI and FLORIAN GORSKI)
Plaintiffs,) No.
v.)
JANSSEN RESEARCH & DEVELOPMENT LLC)
f/k/a JOHNSON AND JOHNSON)
PHARMACEUTICAL RESEARCH AND)
DEVELOPMENT LLC, JANSSEN ORTHO LLC,)
JANSSEN PHARMACEUTICALS, INC. f/k/a)
JANSSEN PHARMACEUTICA, INC. f/k/a)
ORTHO-MCNEIL-JANSSEN)
PHARMACEUTICALS, INC., JOHNSON &)
JOHNSON COMPANY, BAYER HEALTHCARE)
PHARMACEUTICALS, INC., BAYER PHARMA)
AG, BAYER CORPORATION, BAYER)
HEALTHCARE LLC, BAYER HEALTHCARE)
AG, and BAYER AG,)
Defendants.)
JUDGE:

COMPLAINT

Plaintiffs, KEIKO GORSKI and FLORIAN GORSKI, by their attorneys, MOTHERWAY & NAPLETON, LLP, complains of the Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC, et al., as follows:

I. PLAINTIFF'S SPECIFIC ALLEGATIONS

1. Plaintiff, KEIKO GORSKI, was born on January 9, 1934, is a person the full age of majority, and a resident of the State of Illinois, Will County.
 - a. Plaintiff ingested Xarelto beginning in early 2021 through August 2021.
 - b. Plaintiff suffered a syncopal episode resulting in major head trauma on or about August 2, 2021. At the time of injury, Plaintiff resided at 9758 Sorenson Court, Mokena, IL 60448.
 - c. The injuries sustained by Plaintiff were caused by Defendants' Xarelto.

d. In conjunction with Plaintiff's claim, FLORIAN GORSKI, spouse of KEIKO GORSKI, asserts a claim for loss of consortium.

II. JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000, exclusive of interest and costs, and because Defendants are incorporated and have their principal place of business in states other than the State of Illinois where Plaintiff, KEIKO GORSKI, resides.

3. This Court has personal jurisdiction over the Defendants consistent with the United States Constitution as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of Illinois and by virtue of Defendants' substantial continuous and systematic contacts with the State of Illinois unrelated to Plaintiff's claims.

4. Venue is proper in this district under 28 U.S.C. § 1391(b) because Plaintiff resides in this district and Plaintiff ingested Defendants' product in this district. Therefore, a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this district.

II. NATURE OF THE CLAIM

5. This action is brought on behalf of Plaintiff who used Xarelto, also known as rivaroxaban, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

6. Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANS SEN PHARMACEUTICALS, INC., BAYER

HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as “Defendants”) designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto.

7. When warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the “FDA”), to Plaintiff and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

8. Defendants concealed their knowledge of Xarelto's defects, from Plaintiff, the FDA, the public in general and/or the medical community specifically.

9. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public, and the medical and healthcare community and were made with the intent of inducing the public and the medical community to recommend, dispense and/or purchase Xarelto for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff.

10. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Plaintiff, and Plaintiff's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Xarelto whatsoever.

11. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including *inter alia* internal bleeding, as well as other severe and personal injuries, which are/were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

12. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Plaintiff seeks compensatory damages as a result of Plaintiff's use of Xarelto, which caused her injuries.

III. PARTY DEFENDANTS

14. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D's sole member is Janssen Pharmaceuticals, Inc., which is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Accordingly, JANSSEN R&D is a citizen of Pennsylvania and New Jersey for purposes of determining diversity under 28 U.S.C. § 1332. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

15. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

16. Upon information and belief, Defendant JANSSEN R&D has transacted and conducted business in the State of Illinois.

17. Upon information and belief, Defendant JANSSEN R&D has derived substantial revenue from goods and products used in the State of Illinois.

18. Upon information and belief, Defendant JANSSEN R&D expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

19. Upon information and belief, and at all relevant times, Defendant, JANSSEN R&D, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use and an oral anticoagulant, the primary purpose of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

20. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

21. As part of its business, JANSSEN PHARM is involved in the research, development, sales and marketing of pharmaceutical productions including Xarelto and rivaroxaban.

22. Upon information and belief, Defendant, JANSSEN PHARM has transacted and conducted business in the State of Illinois.

23. Upon information and belief, Defendant, JANSSEN PHARM has derived substantial revenue from goods and productions used in the State of Illinois.

24. Upon information and belief, Defendant, JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, more particularly.

25. Upon information and belief, and at all relevant times, Defendant JANSSEN PHARM, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute the drug Xarelto for use as an oral anticoagulant, the primary purpose of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

26. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson. The only member of JANSSEN ORTHO LLC is OMJ PR Holdings, which is incorporated in Ireland with a principal place of business in Puerto Rico. Accordingly, JANSSEN ORTHO LLC is a citizen of Delaware, Ireland and Puerto Rico for purposes of determining diversity under [28 U.S.C. § 1332](#).

27. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

28. Upon information and belief, Defendant, JANSSEN ORTHO has transacted and conducted business in the State of Illinois.

29. Upon information and belief, Defendant, JANSSEN ORTHO, has derived substantial revenue from goods and products used in the State of Illinois.

30. Upon information and belief, Defendant, JANSSEN ORTHO, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

31. Upon information and belief, and at all relevant times, Defendant, JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non- valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

32. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

33. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

34. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

35. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has transacted and conducted business in the State of Illinois.

36. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has derived substantial revenue from goods and products used in the State of Illinois.

37. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

38. Upon information and belief, and at all relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

39. Upon information and belief, Defendant BAYER PHARMA AG is a pharmaceutical company domiciled in Germany.

40. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

41. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

42. Upon information and belief, Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011.

43. As part of its business, BAYER PHARMA AG is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

44. Upon information and belief, Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of Illinois.

45. Upon information and belief, Defendant, BAYER PHARMA AG, has derived substantial revenue from goods and products used in the State of Illinois.

46. Upon information and belief, Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

47. Upon information and belief, and at all relevant times, Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

48. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

49. Upon information and belief, Defendant, BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which

owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC.

50. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription Xarelto.

51. At relevant times, Defendant, BAYER CORPORATION conducted regular and sustained business in the State of Illinois, by selling and distributing its products in the State of Illinois, and engaged in substantial commerce and business activity in the State of Illinois.

52. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey. BAYER HEALTHCARE LLC's sole member is Bayer Corporation, and is wholly owned by Bayer Corporation, which is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Accordingly, BAYER HEALTHCARE LLC is a citizen of Delaware, New Jersey, Indiana and Pennsylvania for purposes of determining diversity under 28 U.S.C. § 1332.

53. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Illinois, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC.

54. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America and in the State of Illinois, and derived substantial revenue from interstate commerce.

55. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

56. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER PHARMA AG.

57. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Illinois, and derived substantial revenue from interstate commerce.

58. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Illinois, and derived substantial revenue from interstate commerce.

59. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION,

BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

60. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

61. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

62. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

63. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Illinois, and derived substantial revenue from interstate commerce.

64. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Illinois, and derived substantial revenue from interstate commerce.

65. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

IV. FACTUAL BACKGROUND

66. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute the drug Xarelto for use as an oral anticoagulant, the primary purpose of which are to reduce the risk of stroke and systemic embolism

in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

67. Defendants received FDA approval for Xarelto, also known as rivaroxaban, on July 1, 2011, for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries (NDA 022406).

68. Defendants then received additional FDA approval for Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation on November 4, 2011 (NDA 202439).

69. The additional indication for treatment of DVT and/or PE and the reduction in recurrence of DVT and./or PE was added to the label on November 2, 2012.

70. Defendants launched Xarelto in the United States (hereinafter referred to as the “U.S.”) in 2011.

71. Xarelto is an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15 mg, and 10 mg.

72. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement and knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the “RECORD” studies). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition), accompanied by similar rates of bleeding. However, the studies also showed a great incidence with Xarelto of bleeding and leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et

al. Rivaroxaban versus Enoxaprin for Thromboprophylaxis after the Total Knee Arthroplasty. N Engl J Med. 2008; 358:2776-86; Kakkar, A.K., et al. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty; a double-blind randomised controlled trial. Lancet 2008; 327:31-39; Ericksson, B.I., et al. Rivaroxaban versus Enoxaprin for Thromboprophylaxis after Hip Arthroplasty. N Engl J Med. 2008;358:2765-75.)

73. Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as “ROCKET AF”). The study's findings showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with similar risk of major bleeding. However, bleeding from gastrointestinal sites, including upper lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion.” (Patel, M.R., et al. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation, N Engl J Med. 2011;365:883-91.)

74. Approval of Xarelto for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, AND EINSTEIN -Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT with obvious increased risk of bleeding events as compared to placebo. (THE EINSTEIN Investigators. Oral Rivaroxaban for Symptomatic Venous Thromboembolism. N Engl J Med.

2010; 363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. *Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study)*. Expert Rev. Cardiovasc. Ther. 2011;9(7):841-844). The EINSTEIN-PE study's findings showed that rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEIN-PE investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism*. N Engl J Med. 2012;366:1287-97.)

75. Defendants use the results of the ROCKET AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

76. Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto Difference -namely, that Xarelto does not require periodic monitoring with blood test and does not limit a patient's diet.

77. However, in its Quarter Watch publication for the first quarter of 2012 fiscal year, the Institute of Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing."

78. Importantly, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

79. Defendants spent significant money in promoting Xarelto, which included at least \$11,000,000 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

80. As a result of Defendants' aggressive marketing efforts, in its first full year of being on the market, Xarelto garnered approximately \$582 million in sales globally.

81. Defendants' website for Xarelto claims that over seven million people worldwide have been prescribed Xarelto. In the U.S. approximately 1 million Xarelto prescriptions had been written by the end of 2013.

82. During the Defendants' 2012 fiscal year, Xarelto garnered approximately \$658 million in sales worldwide. Then in 2013, sales for Xarelto increased even further to more than clear the \$1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately \$2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

83. As part of their making of Xarelto, Defendants widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Plaintiff, to make inquiries to their prescribing physician about Xarelto and/or request prescriptions for Xarelto.

84. In the course of these direct-to-consumer advertisements, Defendants overstated the efficacy of Xarelto with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Xarelto, and that such irreversibility could have permanently disabling, life threatening and fatal consequences.

85. On June 6, 2013, Defendants received an untitled letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading "claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

86. Prior to Plaintiff's prescription of Xarelto, Plaintiff's prescribing physicians received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there were no reversal agent that could stop or control bleeding in patients taking Xarelto.

87. At all times relevant hereto, Defendants also failed to warn patients, emergency room doctors, surgeons, and/or other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Xarelto, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Xarelto.

88. In the year leading up to or about June 30, 2012, there were 1,080 Xarelto-associated “Serious Adverse Event” (“SAE”) Medwatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related death with warfarin.

89. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

90. The ISMP referred to these SAE figures as constituting a “strong signal” regarding the safety of Xarelto, defined as “evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation.”

91. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

92. On a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related adverse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

93. Despite the clear signal generated by the SAE data, Defendants failed to either alert the public and the scientific community, or perform further investigation into the safety of Xarelto.

94. Defendants original and in some respects current labeling and prescribing information for Xarelto:

- a. Failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto; and/or

- b. Failed to provide adequate warnings about the true safety risks associated with the use of Xarelto; and/or
- c. Failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient; and/or
- d. Failed to disclose in the “Warnings” Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto; and/or
- e. Failed to advise prescribing physicians, such as Plaintiff’s physician, to instruct patients that there is no agent to reverse the anticoagulant effects of Xarelto; and/or
- f. Failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto; and/or
- g. Failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto users;
- h. Failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially in those patients with a prior history of gastrointestinal issues and/or upset; and/or
- i. Failed to provide adequate warnings regarding the increased risk of suffering a bleeding event requiring blood transfusions in those taking Xarelto; and/or
- j. Failed to provide adequate warnings regarding the need to access renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto; and/or
- k. Failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto; and/or
- l. Failed to include a “BOXED WARNING” about serious bleeding events associated with Xarelto; and/or
- m. Failed to include a “Bolded Warning” about serious bleeding events associated with Xarelto; and/or
- n. In their “Medication Guide” intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could have permanently disabling, life threatening or fatal consequences; and/or

o. Failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto.

95. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 99 (a-o).

96. Prior to applying for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of life-threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidence Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

97. Upon information and belief, despite life-threatening bleeding findings in a clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Xarelto prior to filing their New Drug Application for Xarelto.

98. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's prescribing physicians that Xarelto was associated with and/or could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

99. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that they have failed to fully test, or study said risk.

100. Upon information and belief, Defendants ignored the association between the use of Xarelto and the risk of developing life-threatening bleeding.

101. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for life-threatening bleeding risk further rendered warnings for this medication inadequate.

102. By reason of the foregoing acts and omissions, Plaintiff seeks compensatory damages as a result of the Plaintiff's use of Xarelto, which caused Plaintiff to suffer from life-threatening bleeding, and Plaintiff suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

103. By reason of the foregoing, Plaintiff has been severely and permanently injured.

104. By reason of the foregoing acts and omissions, Plaintiff has endured and, in some categories continues to suffer, emotional and mental anguish, medical expenses, and other economic and non-economic damages, as a result of the actions and inactions of the Defendants.

V. CLAIMS FOR RELIEF

COUNT I – NEGLIGENCE
Against All Defendants

105. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

106. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Xarelto into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

107. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Xarelto into interstate commerce in that Defendants knew or should have known that using Xarelto created a high risk of unreasonable, dangerous side effects, including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as need for lifelong medical treatment, monitoring, and/or medications.

108. The negligence by the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without thoroughly testing it; and/or
- b. Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without adequately testing it; and/or
- c. Not conducting sufficient testing programs to determine whether or not Xarelto was safe for use; in that Defendants herein knew or should have known that Xarelto was unsafe and unfit for use by reason of the dangers to its users; and/or
- d. Selling Xarelto without making proper and sufficient tests to determine the dangers to its users; and/or
- e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto; and/or
- f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Xarelto; and/or

- g. Failing to test Xarelto and/or failing to adequately, sufficiently and properly test Xarelto; and/or
- h. Negligently advertising and recommending the use of Xarelto without sufficient knowledge as to its dangerous propensities; and/or
- i. Negligently representing that Xarelto was safe for use for its intended, purpose, when, in fact, it was unsafe; and/or
- j. Negligently representing that Xarelto had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence Of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery; and/or
- k. Negligently designing Xarelto in a manner, which was dangerous to its users; and/or
- l. Negligently manufacturing Xarelto in a manner, which was dangerous to its users; and/or
- m. Negligently producing Xarelto in a manner, which was dangerous to its users; and/or
- n. Negligently assembling Xarelto in a manner, which was dangerous to its users; and/or
- o. Concealing information from the Plaintiff in knowing that Xarelto was unsafe, dangerous, and/or non-conforming with FDA regulations; and/or
- p. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Xarelto compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients, which non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

109. Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto.

110. Defendants negligently compared the safety risk and/or dangers of Xarelto with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

111. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Xarelto in that Defendants:

- a. Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery; and/or
- b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Xarelto; and/or
- c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Xarelto; and/or
- d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Xarelto; and/or
- e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects; and/or
- f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto; and/or
- g. Failed to warn Plaintiff, prior to actively encouraging the sale of Xarelto, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and/or
- h. Were otherwise careless and/or negligent.

112. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Xarelto to consumers, including Plaintiff.

113. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

114. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss, which Plaintiff suffered and/or will continue to suffer.

115. As a result of the foregoing acts and omissions, Plaintiff suffered from serious and dangerous side effects including but not limited to, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care. Further, Plaintiff suffered life-threatening bleeding, and Plaintiff suffered severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

116. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT II – STRICT PRODUCTS LIABILITY
Against All Defendants

117. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

118. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, tested, advertised, promoted, marketed, sold and distributed Xarelto as hereinabove described that was used by Plaintiff.

119. Defendants' Xarelto was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

120. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff.

121. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

122. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

123. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

124. Defendants knew or should have known that at all times herein mentioned its Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

125. At the time of Plaintiff's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended, namely, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

126. Defendants with this knowledge voluntarily designed its Xarelto in a dangerous condition for use by the public, and in particular the Plaintiff.

127. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

128. Defendants created a product unreasonably dangerous for its normal, intended use.

129. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

130. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

131. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product, which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

132. Plaintiff could not, by the exercise of reasonable care, have discovered Xarelto's defects herein mentioned and perceived its danger.

133. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

134. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

135. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate postmarketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, life-threatening bleeding, as well as other severe and permanent health consequences from Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Xarelto.

136. By reason of the foregoing, the Defendants have become strictly liable to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Xarelto.

137. Defendants' defective design, manufacturing defect, and inadequate warnings of Xarelto were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

138. That said defects in Defendants' drug Xarelto were a substantial factor in causing Plaintiff's injuries.

139. As a result of the foregoing acts and omission, Plaintiff suffered from life-threatening bleeding, and suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT III – BREACH OF EXPRESS WARRANTY
Against All Defendants

140. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

141. Defendants expressly warranted that Xarelto was safe and well accepted by users.

142. Xarelto does not conform to these express representation because Xarelto is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

143. Plaintiff did rely on the express warranties of the Defendants herein.

144. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Xarelto in recommending, prescribing, and/or dispensing Xarelto.

145. The Defendants herein breached the aforesaid express warranties, as their drug Xarelto was defective.

146. Defendants expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce and dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-vascular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

147. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

148. As a result of the foregoing acts and omissions, Plaintiff suffered from life-threatening bleeding, and Plaintiff suffered severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and financial expenses for hospitalization and medical care.

149. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

COUNT IV – BREACH OF IMPLIED WARRANTIES
Against All Defendants

150. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

151. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and/or have recently acquired the Defendants who have manufactured, compound portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto, to reduce the risk of stroke and systemic embolism in patients with non-vascular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

152. At the time Defendants marketed, sold, and distributed Xarelto for use by Plaintiff, Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be or merchantable quality and safe and fit for such use.

153. The Defendants impliedly represented and warranted to the users of and their physicians, healthcare providers, and/or the FDA that Xarelto was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

154. The representations and warranties aforementioned were false, misleading, and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

155. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for particular use and purpose.

156. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Xarelto was of merchantable quality and safe and fit for its intended use.

157. Xarelto was injected into the stream of commerce by the Defendants in a defective, unsafe and inherently dangerous condition and the products materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold. The factors contributing to the defective, unsafe and inherently dangerous condition include, but are not limited to:

- a. That Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- b. That the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- c. That the risks of adverse events with Xarelto were not adequately tested and/or known by Defense;
- d. That Defendants were aware of dangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

- e. That Xarelto was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- f. That patients needed to be monitored more regularly than normal while using Xarelto;
- g. That Xarelto was manufactured negligently;
- h. That Xarelto was manufactured defectively;
- i. That Xarelto was manufactured improperly;
- j. That Xarelto was designed negligently;
- k. That Xarelto was designed defectively; and
- l. That Xarelto was designed improperly.

158. The Defendants herein breached the aforesaid implied warranties, as their drug Xarelto was not fit for its intended purposes and uses.

159. As a result of the foregoing acts and omissions, Plaintiff suffered from life-threatening bleeding, and Plaintiff suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, financial expenses for hospitalization and medical care, including medical expenses and other economic, and non-economic damages.

COUNT V – FRAUDULENT MISREPRESENTATION
Against All Defendants

160. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

161. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff, and/or the FDA, and the public in general, that said product, Xarelto, had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

162. The representations made by Defendants were, in fact, false.

163. When these representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

164. These representations were made by said Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

165. At the time the aforesaid representations were made by the Defendants and, at the time Plaintiff used Xarelto, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

166. In reliance upon said representations, Plaintiff was induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

167. Defendants knew and were aware or should have been aware that Xarelto had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

168. Defendants knew or should have known that Xarelto had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or downplayed warnings.

169. Defendant brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

170. As a result of the foregoing acts and omissions, Plaintiff suffered from life-threatening bleeding, and Plaintiff suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and financial expenses for hospitalization and medical care.

171. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

COUNT VI – FRAUDULENT CONCEALMENT
Against All Defendants

172. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

173. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Xarelto for its intended use.

174. Defendants knew or were reckless in not knowing that its representations were false.

175. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- a. That Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- b. That the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- c. That the risks of adverse events with Xarelto were not adequately tested and/or known by Defense;
- d. That Defendants were aware of dangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;
- e. That Xarelto was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent

health consequences, in a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

- f. That patients needed to be monitored more regularly than normal while using Xarelto;
- g. That Xarelto was manufactured negligently;
- h. That Xarelto was manufactured defectively;
- i. That Xarelto was manufactured improperly;
- j. That Xarelto was designed negligently;
- k. That Xarelto was designed defectively; and
- l. That Xarelto was designed improperly.

176. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Xarelto, including but not limited to the heightened risks of life-threatening bleeding.

177. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Xarelto, including Plaintiff in particular.

178. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Xarelto was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Xarelto, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Xarelto and/or use the product.

179. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that included material omissions of facts surrounding Xarelto, as set forth herein.

180. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

181. As a result of foregoing acts and omissions, Plaintiff suffered from life-threatening bleeding, and Plaintiff suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and financial expenses for hospitalization and medical care.

182. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

COUNT VII – NEGLIGENT MISREPRESENTATION
Against All Defendants

183. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

184. Defendants have a duty to represent to the medical and healthcare community, and to Plaintiff, the FDA and the public in general that said product, Xarelto, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT, and/or PE and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

185. The representations made by Defendants were, in fact, false.

186. Defendants failed to exercise ordinary care in the representation of Xarelto, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Xarelto's high risk of unreasonable, dangerous side effects.

187. Defendants breached their duty in representing Xarelto's serious side effects to the medical and healthcare community, to Plaintiff, the FDA and the public in general.

188. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death, and financial expenses for hospitalization and medical care.

189. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

COUNT VIII – FRAUD AND DECEIT
Against All Defendants

190. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

191. Defendants conducted research and used Xarelto as part of their research.

192. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Xarelto was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

193. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including Plaintiff.

194. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

195. The information distributed to the public, the FDA, and Plaintiff, by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

196. The information distributed to the public, the FDA, and Plaintiff, by Defendants intentionally included representations that Defendants' drug Xarelto was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

197. The information distributed to the public, the FDA, and Plaintiff, by Defendant intentionally included representations that Defendants' drug Xarelto carried the same risks, hazards, and/or dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

198. The information distributed to the public, the FDA, and Plaintiff, by Defendants intentionally included false representations that Xarelto was not injurious to the health and/or safety of its intended users.

199. The information distributed to the public, the FDA, and Plaintiff, by Defendants intentionally included false representations that Xarelto was as potentially injurious to the health and/or safety of its intended as other forms of treatment for reducing the risk of stroke and systemic

embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

200. These representations were all false and misleading.

201. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Xarelto was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillations, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

202. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and Plaintiff, regarding the safety of Xarelto, specifically but not limited to Xarelto not having dangerous and serious health and/or safety concerns.

203. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and Plaintiff, regarding the safety of Xarelto, specifically but not limited to Xarelto being a safe means of reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

204. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or Plaintiff, to falsely ensure the quality and fitness for use of Xarelto and induce the public, and/or Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Xarelto.

205. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff, that Xarelto was fit and safe for use as a treatment for the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

206. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff, that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

207. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and Plaintiff, that Xarelto did not present serious health and/or safety risks.

208. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and Plaintiff, that Xarelto did not present health and/or safety risks greater than other oral forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

209. These representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

210. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce Plaintiff, and/or her respective healthcare professionals to rely upon misrepresentations and caused Plaintiff, to purchase, use, rely on, request, dispense, recommend, and/or prescribe Xarelto.

211. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to the public at large, Plaintiff, in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

212. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Xarelto.

213. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling Plaintiff, as well as her respective healthcare professionals, into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Xarelto and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

214. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

215. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Xarelto.

216. Plaintiff, and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Xarelto.

217. At the time the representations were made, Plaintiff, and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Xarelto.

218. Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could Plaintiff, with reasonable diligence, have discovered the true facts.

219. Had Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Xarelto, Plaintiff would not have purchased, used and/or relied on Defendants' drug Xarelto.

220. Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on Plaintiff.

221. As a result of the foregoing acts and omissions, Plaintiff suffered life-threatening bleeding, and Plaintiff suffered severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and financial expenses for hospitalization and medical care.

222. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

COUNT IX – UNJUST ENRICHMENT
Against All Defendants

223. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

224. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and ingestion of Xarelto by Plaintiff.

225. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with the full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature or fitness that had been represented by Defendants, or that Plaintiff, as a responsible consumer, expected to receive.

226. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled in equity and hereby seeks the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT X – PUNITIVE DAMAGES
Against All Defendants

227. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, which the same force and effect as if more fully set forth herein.

228. At all material times, the Defendants knew or should have known that Xarelto was inherently dangerous.

229. Despite their knowledge, the Defendants continued to aggressively market Xarelto to consumers, including Plaintiff, without disclosing its dangerous side effects.

230. Despite Defendants' knowledge of Xarelto's defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute Xarelto, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Xarelto.

231. Defendants' conduct was intentional and/or wanton.

232. Defendants' conduct as described herein, including, but not limited to, their failure to adequately test their product, to provide adequate warnings, and their continued manufacture, sale, and marketing of Xarelto when they knew or should have known of the serious health risks, evidences a flagrant disregard for human life as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff.

233. As a proximate result of Defendants' acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other

severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment.

234. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

COUNT XI – VIOLATION OF CONSUMER PROTECTION/FRAUD LAWS
Against All Defendants

235. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading the same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

236. Plaintiff used Xarelto and suffered ascertainable losses as a direct result of Defendants' actions in violation of the consumer protection laws.

237. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have; and/or
- b. Advertising goods or services with the intent not to sell them as advertised; and/or
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

238. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Xarelto.

239. Defendants violated consumer protection laws of various states.

240. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side effects related to the use of Xarelto and of the

true state of Xarelto's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

241. Defendants' conduct in connection with Xarelto was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

242. As a result of these violations of consumer protections laws, Plaintiff has incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expenses related to the diagnosis and treatment thereof, for which Defendants are liable.

COUNT XII – LOSS OF CONSORTIUM
Against All Defendants

243. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

244. At all relevant times hereto, where applicable, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") who has suffered injuries and losses as a result of the Plaintiff's injuries from Xarelto.

245. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring,

medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

246. For the reasons set forth herein, Spouse Plaintiff has suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

247. Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

248. Spouse Plaintiff has suffered great emotional pain and mental anguish.

249. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiff jointly and severally for all general, special and equitable relief to which Spouse Plaintiff is entitled by law.

VI. PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs, KEIKO GORSKI and FLORIAN GORSKI, demand judgment against Defendants on each of the above claims and causes of action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
2. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to Plaintiff's pain and suffering and Plaintiff's pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health care costs and economic loss;
3. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determine at trial of this action;
4. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless

indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct, to the extent allowed by applicable law;

5. Pre-judgment interest;
6. Post-judgment interest;
7. Awarding Plaintiff's reasonable attorneys' fees;
8. Awarding Plaintiff the costs of these proceedings; and
9. Such other and further relief as this Court deems just and proper.

VII. JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all issues.

Respectfully submitted,



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